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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,826	10/20/2003	Mark Alan Jackson	60497.000009	9915

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EXAMINER	
MARTINEZ, BRITTANY M	
ART UNIT	PAPER NUMBER
1793	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,826	JACKSON, MARK ALAN	
	Examiner	Art Unit	
	BRITTANY M. MARTINEZ	1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *13-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 29-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 7, 2008 has been entered.

Status of Application

Applicant's arguments/remarks and amendments filed on August 7, 2008, have been carefully considered. **Claims 1-34** are pending in this application, with **Claims 1-2, 6, 9, and 11** amended and **Claims 29-34** added. **Claims 1-12 and 29-34** have been examined and **Claims 13-28** withdrawn in view of the restriction requirement made August 2, 2007.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office action.

1. **Claims 1-3, 5, and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602) in view of Bergstrom et al. (US 6,445,146).

2. With respect to **Claim 1**, Dabiri teaches a transportable radioisotope production facility that produces radioisotopes having application to Positron Emission Tomography (PET) (Dabiri, Claims 1, 4, and 13).

3. As to **Claims 2-3**, Dabiri discloses a radioisotope production facility with a "...radiopharmaceutical subsystem that prepares suitable radiopharmaceuticals from precursors containing the radioisotopes" produced via a particle accelerator (Dabiri, "Abstract", limitations c-d of Claim 13, and Fig. 1).

4. With regard to **Claim 5**, Dabiri teaches a method for producing radiopharmaceuticals suitable for use with a PET system (Dabiri, c. 4, l. 3-5).

Dabiri does not explicitly disclose a cyclotron (**Claim 1**); a laboratory where the synthesis unit is located (**Claim 2**); or the step of equipping the manufacturing facility with a clean room for dispensing the second radioactive material into one or more containers prior to transporting the manufacturing facility to the site (**Claim 29**).

5. With regard to **Claim 1**, a radio frequency quadruple (RFQ) linear accelerator is taught as the particle accelerator of choice because typical cyclotrons are too massive for the restricted space available in a transportable radioisotope production facility

(Dabiri, c. 4, l. 3-5). Bergstrom discloses a compact cyclotron (MINItrace™) suitable for installation in a PET isotope production facility with limited space (Bergstrom, c. 2, l. 64-67, and c. 3, l. 1-5). A person of ordinary skill in the art would recognize from the teachings of Dabiri that cyclotrons are more typically used in PET isotope production systems over RFQ linear accelerators (Dabiri, c. 1, l. 59-68, and c. 2, l. 1-4). When Dabiri is modified in view of Bergstrom, one would have been motivated to make such modifications because the space limitations presented by an ordinary cyclotron in a transportable facility (Dabiri, c. 2, l. 49-68) could be overcome by a more compact cyclotron (Bergstrom, c. 2, l. 64-67, and c. 3, l. 1-5 and 60-65).

6. With regard to **Claim 2**, it is conventional to place a synthesis unit in a laboratory. Thus, including a laboratory in the radioisotope production facility of Dabiri would have been obvious to one of ordinary skill in the art.

7. With regard to **Claim 29**, it is conventional practice to equip a radioactive material production facility with a clean room for dispensing the radioactive material into containers.

8. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602) in view of Bergstrom et al. (US 6,445,146) as applied to **Claim 2** above, and further in view of Applicant's own disclosure.

9. With regard to **Claim 4**, Dabiri discloses the production of an ^{18}F isotope via an acceleration system (Dabiri, "Abstract").

10. Dabiri does not explicitly disclose the production of a 2-[^{18}F]-fluoro-2-deoxyglucose radiopharmaceutical from the ^{18}F isotope via the radiopharmaceutical synthesis subsystem (**Claim 4**).

11. With regard to **Claim 4**, in Applicant's own disclosure, Applicant has admitted "…^{18}F is commonly converted to ^{18}FDG (2-[^{18}F]-fluoro-2-deoxyglucose)…" (S. 5, 0024). Applicant also cites K. Hamacher, H.H. Coenen and G. Stocklin, J. Nucl. Med. 27, 235-238 (1986) for further details regarding "Addiional details of this well known process…" (S. 6, 0031). This art teaches that "In conjunction with positron emission tomography (PET), 2-[^{18}F]-fluoro-2-deoxy-D-glucose (2-FDG) is presently the most important radiopharmaceutical…" (K. Hamacher, H.H. Coenen and G. Stocklin, J. Nucl. Med. 27, 235 (1986)). A person of ordinary skill in the art would recognize from the teachings of Dabiri that the "suitable radiopharmaceutical" produced from the ^{18}F isotope obtained via an acceleration system such as a cyclotron system would be a variation of [^{18}F]-fluorodeoxyglucose (Dabiri, "Abstract" and Goodman, 2, 14-16).

12. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602) in view of Bergstrom et al. (US 6,445,146) as applied to **Claim 1** above, and further in view of Wiberg et al. (US 6,392,246).

13. Dabiri does not explicitly disclose a radiation shielded manufacturing facility (**Claim 7**).

14. With regard to **Claim 7**, Wiberg discloses an integrated radiation shield for a PET isotope production system containing a cyclotron (Wiberg, "Abstract"). Further, the

compact cyclotron taught by Bergstrom includes an integrated radiation shield for a PET isotope production system (Bergstrom, c. 2, l. 64-67; c. 3, l. 1-5 and 65-67; and c. 4, l. 1-2). A person of ordinary skill in the art would recognize that substituting a cyclotron for the RFQ linear accelerator taught by Dabiri would necessitate integration of radiation shielding similar to that taught by Wiberg or Bergstrom into the transportable radioisotope manufacturing facility.

15. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602) in view of Bergstrom et al. (US 6,445,146) as applied to **Claim 1** above, and further in view of Strawson (US 6,437,344).

16. Dabiri does not explicitly disclose a radiation shielded manufacturing facility (**Claim 8**).

17. With regard to **Claim 8**, Strawson discloses that although the facility may be entirely self-contained, the device may be shipped as two or more subassemblies and reassembled on site (Strawson, c. 31, l. 53-55). It would be obvious to a person of ordinary skill in the art to install radiation shielding in the walls of the facility post transportation if this would ease transportation to the site or if this was a result of increased shielding requirement regulations at the site.

18. **Claims 6 and 9-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602) in view of Bergstrom et al. (US 6,445,146) as applied

to **Claims 1-2** above, and further in view of Ashley et al. (US 4,428,908), Zhu et al. (US 5,927,351), and Armel (US 3,411,002).

19. With respect to **Claims 6 and 10**, Dabiri generally discloses an entirely transportable system (Dabiri, Claim 4). Dabiri does not explicitly disclose packaging or containment equipment to be used with the radiopharmaceuticals produced in the transportable facility; or labeling of the vials containing the second radioactive material. Armel teaches the use of on-site containers for radioactive materials as associated equipment in the completely self-contained unit (Armel, c. 2, l. 18-30). Zhu discloses that radiopharmaceuticals utilized in PET systems are typically very radioactive and necessitate heavily shielded transport containers (Zhu, c. 1, l. 53-67). A person of ordinary skill in the art would recognize the necessity for specialty packaging/containment as taught by Zhu, and realize that if a facility is entirely transportable and self-contained as disclosed by Dabiri and Armel, respectively, the manufacturing facility would have to be equipped with the packaging equipment and associated packaging room prior to transporting the facility to its designated site (Dabiri, Claim 4; Armel, c. 2, l. 18-30; and Zhu c. 1, l. 53-67). Further, it is conventional to label vials in any chemical synthesis process.

20. With respect to **Claim 9**, Dabiri does not teach equipping the manufacturing facility with quality control equipment to measure the quality of the second radiopharmaceutical. Ashley discloses impurities in radiopharmaceuticals are well known in the art, and the presence of such impurities increases radiation doses to non-target organs and contributes to poor quality clinical images when used in nuclear

medicine (Ashley, c. 1, l. 15-24). Ashley further teaches the "...invaluable benefit in instituting a program of quality control" (Ashley, c. 1, l. 15-24). A person of ordinary skill in the art would recognize that equipping the transportable manufacturing facility with quality control equipment as taught by Ashley would be obvious. With respect to **Claim 11**, Dabiri implies a communications port for remote monitoring the manufacturing facility through the disclosure of a technician-initiated control subsystem that provides control signals for automatic operation of the particle accelerator and targetry (Dabiri, c. 6, l. 18-27). Dabiri further teaches a production process support system monitored and controlled by a technician (Dabiri, c. 14, l. 36-56, and Claim 10). Where Dabiri does not explicitly teach a communications port connected to at least one sensor on the cyclotron, Bergstrom teaches a feedback system-controlled radio frequency (RF) generation system and a cyclotron controller system for control of "...the electromagnetic field in relation to the accelerating RF field frequency for creating the optimum operation conditions for the created beam of negative hydrogen ions" (Bergstrom, c. 6, l. 32-35). A cyclotron control system would be necessary for communication with the cyclotron enclosed in the manufacturing facility.

21. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602) in view of Bergstrom et al. (US 6,445,146) as applied to **Claim 3** above, and further in view of Wiberg et al. (US 6,392,246) and Zhu et al. (US 5,927,351).

22. Dabiri does not disclose that the manufacturing facility must "satisfy all legal and regulatory requirements of the jurisdiction in which the site is located" (**Claim 12**). Wiberg teaches that all radiation hazard regulations have to be followed for PET isotope production systems (Wiberg, c. 1, l. 18-21). Zhu teaches further that radiopharmaceuticals should be handled according to U.S. Department of Transportation, Nuclear Regulatory Commission, and Occupational Health and Safety Administration regulations (Zhu, c. 1, l. 21-27). It would be obvious to a person of ordinary skill in the art to ensure that the manufacturing facility complied with all legal and regulatory requirements of the jurisdiction in which the site is located, as taught by Wiberg and Zhu.

23. **Claims 30-34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dabiri et al. (US 5,037,602) in view of Bergstrom et al. (US 6,445,146), Ashley et al. (US 4,428,908), Zhu et al. (US 5,927,351), and Armel (US 3,411,002).

24. With respect to **Claim 30**, Dabiri teaches a transportable radioisotope production facility that produces radioisotopes having application to Positron Emission Tomography (PET) (Dabiri, Claims 1, 4, and 13). Dabiri further discloses a radioisotope production facility with a "…radiopharmaceutical subsystem that prepares suitable radiopharmaceuticals from precursors containing the radioisotopes" produced via a particle accelerator (Dabiri, "Abstract", limitations c-d of Claim 13, and Fig. 1).

25. Dabiri does not explicitly disclose a cyclotron (**Claim 30**); a packaging area/packaging equipment to be used with the radiopharmaceuticals produced in the

transportable facility (**Claims 30 and 33**); the packaging area allowing for labeling of the vials containing the radiopharmaceutical and entering of records of production and delivery of the pharmaceutical; the manufacturing facility being designed to satisfy substantially all legal and regulatory requirements of the jurisdiction in which the site is located (**Claim 30**); a laboratory where the synthesis unit is located (**Claim 31**); or the step of equipping the manufacturing facility with a clean room for dispensing the radiopharmaceutical into one or more containers prior to transporting the manufacturing facility to the site (**Claim 34**).

26. With regard to **Claim 30**, a radio frequency quadruple (RFQ) linear accelerator is taught as the particle accelerator of choice because typical cyclotrons are too massive for the restricted space available in a transportable radioisotope production facility (Dabiri, c. 4, l. 3-5). Bergstrom discloses a compact cyclotron (MINItrace™) suitable for installation in a PET isotope production facility with limited space (Bergstrom, c. 2, l. 64-67, and c. 3, l. 1-5). A person of ordinary skill in the art would recognize from the teachings of Dabiri that cyclotrons are more typically used in PET isotope production systems over RFQ linear accelerators (Dabiri, c. 1, l. 59-68, and c. 2, l. 1-4). When Dabiri is modified in view of Bergstrom, one would have been motivated to make such modifications because the space limitations presented by an ordinary cyclotron in a transportable facility (Dabiri, c. 2, l. 49-68) could be overcome by a more compact cyclotron (Bergstrom, c. 2, l. 64-67, and c. 3, l. 1-5 and 60-65).

27. Further with respect to **Claims 30 and 33**, Dabiri generally discloses an entirely transportable system (Dabiri, Claim 4). Armel teaches the use of on-site containers for

radioactive materials as associated equipment in the completely self-contained unit (Armel, c. 2, l. 18-30). Zhu discloses that radiopharmaceuticals utilized in PET systems are typically very radioactive and necessitate heavily shielded transport containers (Zhu, c. 1, l. 53-67). A person of ordinary skill in the art would recognize the necessity for a specialty packaging area as taught by Zhu, and realize that if a facility is entirely transportable and self-contained as disclosed by Dabiri and Armel, respectively, the manufacturing facility would have to be equipped with the packaging equipment and associated packaging room prior to transporting the facility to its designated site (Dabiri, Claim 4; Armel, c. 2, l. 18-30; and Zhu c. 1, l. 53-67). Further, it is conventional to label vials and enter records of the production and delivery of products produced in any chemical synthesis process.

28. With regard to **Claim 30**, it is conventional practice to design a facility to satisfy substantially all legal and regulatory requirements of the jurisdiction in which the site is located.

29. With regard to **Claim 31**, it is conventional to place a synthesis unit in a laboratory. Thus, including a laboratory in the radioisotope production facility of Dabiri would have been obvious to one of ordinary skill in the art.

30. With respect to **Claim 32**, Dabiri does not teach equipping the manufacturing facility with quality control equipment to measure the quality of the second radiopharmaceutical prior to transporting the manufacturing facility to the site. Ashley discloses impurities in radiopharmaceuticals are well known in the art, and the presence of such impurities increases radiation doses to non-target organs and contributes to

poor quality clinical images when used in nuclear medicine (Ashley, c. 1, l. 15-24). Ashley further teaches the "...invaluable benefit in instituting a program of quality control" (Ashley, c. 1, l. 15-24). A person of ordinary skill in the art would recognize that equipping the transportable manufacturing facility with quality control equipment as taught by Ashley would be obvious.

31. With regard to **Claim 34**, it is conventional practice to equip a radioactive material production facility with a clean room for dispensing the radioactive material into containers.

Response to Amendments

Applicant's amendments, filed August 7, 2008, with respect to the claims have been fully considered and are accepted.

Response to Arguments

1. Applicant's arguments regarding the Claim Rejections under 35 U.S.C. § 103, filed August 7, 2008, have been fully considered but they are not persuasive.

2. Applicant's arguments regarding Dabiri teaching away from replacing the RFQ with a cyclotron (Dabiri claims less shielding necessary for the RFQ; the amount of power consumed by the RFQ being less than a cyclotron; the amount of neutron production by the RFQ being less than a cyclotron; extraction not required for RFQ; the beam activation problems of the cyclotron being eliminated with the RFQ, etc.) are acknowledged. However, one cannot show nonobviousness by attacking references

individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, it would have been obvious to one of ordinary skill in the art to modify the transportable radioisotope production facility of Dabiri with the cyclotron of Bergstrom and Wilson because the limitations presented by an ordinary cyclotron in a transportable facility (Dabiri, column 2, lines 49-68) could be overcome by a more compact cyclotron (Bergstrom, column 2, lines 64-67; column 3, lines 1-5 and 60-65).

3. In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

4. Applicant's arguments with respect to Bergstrom teaching away from the cyclotron of Wilson have been considered but are moot in view of the new ground(s) of rejection.

5. In response to Applicant's arguments regarding the new claims failing to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e., the packaging area allowing for labeling of containers) were not

recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). With regard to claim 2, the added verbiage adds nothing at all to the claims because the synthesis unit was somewhere before. Merely calling that location a 'laboratory room' is merely a label and does not require anything new. With regard to claim 6, the added verbiage does not add anything beyond that which a technician would prudently have on hand. Suffice it to say that applicant should not expect to obtain a patent by reciting like standard laboratory equipment one would expect to find in a lab- especially a lab which processes radioactive waste. Claim 9 does not recite what is being measured (quantity? weight? B-emmission?) and does not impart patentability.

Conclusion

1. No claim is allowed.

2. In general, prior art renders the claimed invention obvious. See above.

3. Applicant is required to provide pinpoint citation to the specification (i.e. page and paragraph number) to support any amendments to the claims in all subsequent communication with the examiner. **No new matter will be allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRITTANY M. MARTINEZ whose telephone number is (571) 270-3586. The examiner can normally be reached Monday-Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley Silverman can be reached at (571) 272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMM

/Brittany M Martinez/
Examiner, Art Unit 1793

/Stuart Hendrickson/
Primary Examiner, Art Unit 1793